

REMARKS

Claims 14-19 and 21 are pending in the above-referenced application. In the office action dated September 10, 2003 claims 14-16, 18 and 19 were rejected under 35 U.S.C. § 102(b). Claims 17 and 21 were acknowledged as free from prior art. For the reasons explained in more detail below, Applicants respectfully request that the outstanding rejections be withdrawn.

The Examiner rejects claims 14-16, 18 and 19 under 35 U.S.C. § 102(b) as anticipated by Kastern *et al.*, (1990) in light of “Sequence Search Result #2,” and asserts “Sequence Search Result #2 . . . is set forth in the publication of Kastern *et al.*”

Applicants respectfully submit that the bibliographic data for the cited references in search result #2 are misleading and have caused the Examiner to infer incorrectly that a particular sequence was disclosed in both Kastern *et al.* (1990) and Björck (1992) (also referred to as Kastern (1992)). However, an examination of the underlying documents reveals that the recited database sequence was only disclosed in the later (1992) reference, which is not prior art. (Hellebust Declaration Par. 10.) By contrast only fragments were disclosed by the earlier reference; specific areas of the cited sequence are absent. (Hellebust Declaration Par. 10.) As described more fully below, when the pending claims are viewed in light of the Kastern *et al.* (1990) reference and not the search results, it becomes apparent that the pending claims are not taught, disclosed or otherwise suggested by the cited reference.

The claims of the present application are directed to isolated proteins having the ability to bind to the light chain of immunoglobulins consisting essentially of the amino acid sequence of SEQ ID NO:1, or any of the domains B1, B2, B3 or B4, which are portions of SEQ ID NO:1 or a protein consisting essentially of a multiple of these domains. The claims are further directed to hybrid proteins consisting essentially of one or more of the B1-B4 domains together with domains that bind to heavy chains of immunoglobulin G, reagent kits comprising a protein of the invention and detection agent, and compositions comprising the peptide and additive or carrier.

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Applicants submit that Kastern *et al.* (1990), does not teach, disclose or otherwise suggest any of the proteins claimed.

As explained in paragraph 8 of the Declaration of Dr. Hellebust, the cited reference, Kastern *et al.* (1990), is concerned with the characterization of the bacterial immunoglobulin-binding protein known as protein L. The cited reference discloses the cloning and sequence determination of a part of the protein gene (pp. 1219-1220), and it discloses a sequence of some 220 nucleotides in Figure 5. However, this is not a complete characterization of the protein L gene. The complete sequence of the protein L gene and corresponding amino acid sequence were only reported subsequently by Kastern, Sjöbring & Björck, J. Biolog. Chem. (1992). It has already been established that that 1992 paper by Kastern *et al.* is not prior art (paragraph 5 of the office action dated January 29, 2002).

In relation to the sequence that is disclosed in Kastern *et al.* (1990), as Dr. Hellebust confirms, this is a small fragment of the complete protein L gene. (Hellebust Declaration Par. 9.) It does not correspond to the complete sequence of SEQ ID NO:1, and although it corresponds to a part of that sequence it does not include, in their entirety any of the immunoglobulin-binding domains B1-B4. Thus, Kastern *et al.* (1990) does not disclose the complete sequences of the amino acids 1 to 305 of SEQ ID NO:1, amino acids 5 to 80 of SEQ ID NO:1 corresponding to the B1 domain, amino acids 81 to 152 of SEQ ID NO:1 corresponding to the B2 domain, amino acids 153 to 224 of SEQ ID NO:1 corresponding to the B3 domain and amino acids 225 to 296 of SEQ ID NO:1 corresponding to the B4 domain. (Hellebust Declaration Par. 10.)

Notably, figure 5 of Kastern *et al.* (1990), which is the longest sequence of the cited reference, does not disclose amino acids 1 to 108 and 183 to 305 of SEQ ID NO:1, any of B1, amino acids 81 to 108 of B2, amino acids 183 to 224 of B3, or any of B4. It appears that the sequence search results may have been arrived at by comparison with the sequence disclosed in the later paper by Kastern *et al.* from 1992, which is not prior art. Dr. Hellebust, a person of at least ordinary skill in the art has

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reviewed the underlying references, and concluded from the Kastern *et al.* (1990) reference itself, that it is clear that the reference does not disclose either the sequence of SEQ ID NO:1 or the sequences of any of the immunoglobulin-binding domains B1-B4.

Dr. Hellebust further confirms that the disclosed sequences would not be expected to bind the light chains of immunoglobulins. (Hellebust Declaration Par. 11.)

Finally, with regard to a hybrid protein as defined in claim 15, the Examiner argued that such hybrid proteins were also disclosed in Kastern *et al.* (1990). Again, Applicants respectfully disagree. Claim 15 is directed to a specific type of hybrid protein that consists essentially of one or more of the B1-B4 domains of protein L that bind to immunoglobulin light chains and domains that bind to heavy chains of immunoglobulin G. As confirmed in paragraph 11 of Dr Hellebust's Declaration, there is no disclosure of a hybrid protein comprising domains of protein L that bind to the light chain of immunoglobulins and domains that bind to the heavy chains of immunoglobulin G. Nowhere in Kastern *et al.* (1990) is there any disclosure of a hybrid protein incorporating both these components.

In summary, Kastern *et al.* (1990) discloses a nucleotide sequence and corresponding amino acid sequence of only a short fragment of protein L. It does not disclose the complete protein L sequence. Moreover, the specific fragment disclosed by the reference does not correspond to the protein binding domains identified in the present application. It does not correspond to the specific sequence of SEQ ID NO: 1 or the complete sequence of any of the individual binding domains B1-B4. Further, Kastern *et al.* (1990) does not disclose a hybrid protein based on the proteins of the invention in conjunction with domains that bind to the heavy chain of immunoglobulin G.

It is therefore submitted that the cited reference does not disclose either an isolated protein having the ability to bind to the light chains of immunoglobulins as

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defined in claim 14 or a hybrid protein as defined in claim 15 or 16. Thus, it cannot disclose a reagent kit or composition as defined in claim 18 or 19. Accordingly, it is submitted that the subject matter claimed is not anticipated by Kastern *et al.* (1990) and that the pending claims are in condition for allowance.

Favorable reconsideration is therefore respectfully requested.

It is submitted that no fees are due other than the accompanying fees for the petition for an extension of time, and the Notice of Appeal. If any additional fee is due, or an overpayment has been made, the Patent Office is hereby authorized to charge or to credit Deposit Account No. 11-0171 for such sum.

Respectfully submitted



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